PCV4

CLINICAL AND COST OUTCOMES OF VENOUS THROMBOEMBOLISM IN PATIENTS WHO UNDERWENT MAJOR ORTHOPEDIC SURGERY

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OBJECTIVES: To evaluate the effects of venous thromboembolism (VTE) occurring within 30 days of hospital discharge after major orthopedic surgery on inpatient costs and mortality within 1 year after initial hospitalization for the surgery. **METHODS:** U.S. national Medicare data was used for this analysis. All patients who underwent total hip replacement (THR) (n = 51,108) or total knee replacement (TKR) (n = 115,627) surgery were identified. VTE events were diagnosed within the first 30 days and within 1 year post-discharge. Multivariate regression was used to control for differences in baseline characteristics in patients with and without VTE events. Total cost was measured as Medicare cost plus beneficiary out-of-pocket cost. **RESULTS:** VTE occurred in 0.74% of patients undergoing THR. For patients with VTE versus no VTE, mortality was higher (2.9% vs. 0.4%, $P < 0.001$). Medicare and total health care cost, including the beneficiary cost share in 1 year, were not different for VTE versus no VTE ($19,300 vs. $19,044, $p = 0.817$), but the beneficiary cost share was higher for VTE ($3,274 vs. $1,966, $P < 0.001$). VTE occurred in 0.70% of patients undergoing TKR. For patients with VTE versus no VTE, mortality was higher (2.5% vs. 0.15%, $P < 0.001$). Total health care cost, including the beneficiary cost share in 1 year, was not different for VTE versus no VTE ($17,970 vs. $16,766, $p = 0.142$), but the Medicare and beneficiary cost shares were both slightly higher for VTE ($3,274 vs. $1,966 and $2,650 vs. $1,630 for THR and TKR patients, respectively, $P < 0.001$). **CONCLUSIONS:** VTE after major orthopedic surgery is associated with higher mortality compared with no VTE. VTE did not affect total health care costs in 1 year, but beneficiary costs were higher. Risk-adjusted total, Medicare, and beneficiary health care costs were significantly higher for major orthopedic surgery patients with VTE ($P < 0.001$).

PCV5

COMPARISON OF ADVERSE EVENTS OF MEDICARE PATIENTS WHO UNDERWENT KNEE REPLACEMENT SURGERY AND EXPERIENCED VENOUS THROMBOEMBOLISM VERSUS NO VENOUS THROMBOEMBOLISM

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OBJECTIVES: To estimate re-hospitalization and bleeding rates during the 30 days after a venous thromboembolism (VTE) event in patients who underwent knee replacement surgery and to compare the outcomes with patients who did not suffer VTE. **METHODS:** Based on 2004–2006 national Medicare claims, all patients who underwent knee replacement surgery were identified. The 30 days follow-up event rates for patients who had a VTE event during their initial hospitalization were calculated. Events were compared between patients who suffered a VTE event and those who did not. Risk adjustment was done using propensity score matching (using the ProbChoice™ algorithm) controlling for baseline demographic and clinical characteristics between patients with and without VTE. **RESULTS:** In patients who underwent total knee replacement surgery (n = 104,952), 1.9% had post-operative VTE events during their initial hospitalization. Almost 69% (n = 1377) of these patients had deep vein thrombosis (DVT), 25% (n = 501) had pulmonary embolism (PE), and 6% (n = 119) had both DVT and PE. The overall likelihood of mortality was four times higher for VTE patients versus those without VTE (1.35% vs. 0.35%). Patients with VTE during their initial hospitalization were more likely to be hospitalized in 30 days compared to patients without an event during the same hospital stay (16.62% vs. 8.00%). In 30 days after the event, patients with VTE were more likely to have bleeding (9.31% vs. 2.18%). **CONCLUSIONS:** VTE events during initial hospitalization for total knee replacement surgery patients increased the adverse events compared with no VTE events.

PCV6

OUTCOME OF ADVERSE DRUG REACTIONS REGISTERED WITH INTENSIVE MONITORING SYSTEM

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OBJECTIVES: Adverse drug reactions (ADR) appear more frequently then what is actually reported and registered. The aim was to establish intensive monitoring system and to analyze ADR in hospitalized patients. **METHODS:** Prospective study covered 200 patients hospitalized in Cardiology Center, Clinical Center of Montenegro. ADR were collected in the following way: patients were interviewed on the basis of the symptoms list and any signs which could point to eventual ADR. Secondly, lab tests and other available parameters were observed. **RESULTS:** At the time when interviews took place, patients received on average 7.96 ± 2.63 medicines (2–17). In total, 67 patients (34%) had 75 ADR. Twenty-one ADR (28%) are classified as serious. Fifty-four ADR have resulted in the recovery of the patient (72%), eight had as an outcome prolonged hospitalization (11%), another 8 were life threatening (11%), while 5 ADR (6%) were the cause of the hospitalization. The most frequent ADR which had as an outcome admission to hospital were caused by digoxin (40%), prolonged hospital stay by furosemide (38%), while the most frequent registered ADR which were life threatening were caused by streptokinase (50%). **CONCLUSIONS:** Monitoring ADR in patients using cardiovascular drugs is a matter of importance since this class of medicine is usually used by elderly patients with critical conditions and underlying diseases.

PCV7

SPONTANEOUS REPORTING OF ADVERSE DRUG REACTIONS INVOLVING HOSPITALIZED CARDIAC PATIENTS

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OBJECTIVES: Adverse drug reactions (ADR) in hospital are a significant cause of morbidity and mortality. The aim is to analyze the ADR which have been collected through doctors' and medical technicians' spontaneous reporting. **METHODS:** The prospective study covered 655 patients hospitalized in Cardiology Center of Clinical Center of Montenegro. ADR were collected by spontaneous reporting. According to the criteria of World Health Organization, for every ADR causality assessment, severity, type, outcome, level of intervention and place of manifestation of ADR was established. **RESULTS:** In the 6 month period of research at the Cardiology Center, 655 patients were hospitalized with the average age of 60.72 ± 11.36 years. With spontaneous reporting, 22 patients had 22 ADR which were noted. Doctors reported a statistically significant larger number of ADR (68%) than medical technicians (32%), $P < 0,01$. Nine patients (41%) had serious ADR with the following outcome: 21 ADR were the cause of the hospitalization (22%), four ADR resulted in the extended hospitalization (44%), and 3 were life threatening (33%). The most frequent serious ADR were reported spontaneously by doctors and medical technicians and were caused by streptokinase (33%). The most frequent symptoms which the patients had as a consequence of ADR were: fainting (27%), headache (18%), weakness (14%), vertigo (14%) and vomiting (9%). **CONCLUSIONS:** Considering increased use of cardiovascular drugs and limitations in pre-marketing trials for drug safety evaluation, post marketing evaluation of adverse drug reactions induced by this class of medicinal products seems necessary.

PCV8

EVALUATION OF CLINICAL AND DIRECT ECONOMIC OUTCOMES FOLLOWING AN ACUTE CORONARY EVENT AMONG PATIENTS WITH SUBOPTIMAL HDL-C OR TRIGLYCERIDES ADMINISTERED EITHER STATIN AND NIACIN EXTENDED-RELEASE OR STATIN MONOTHERAPY

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OBJECTIVES: To compare the risk of subsequent coronary event (SCE) and associated costs between patients maintaining statin monotherapy (SM) or augmenting with niacin extended-release (NER) after an acute coronary event (ACE). **METHODS:** Patients with an ACE between January 1, 2004 and March 31, 2009 were identified (Index Date was defined as the earliest ACE). Patients age ≥18, ≥6 months eligibility pre- and post-Index Date, ≥1 statin fill and no statin augmenting fill 6 months before the Index Date, and sub-optimal baseline HDL-C (<40 or <50 mg/dL for men and women) or triglyceride (>150 or >200 mg/dL for diabetic and non-diabetic) were included. Cohorts were determined based on NER or SM fills within 6 months of the Index Date (Cohort ID Period). Patients with alternative lipid agents or SCE during the Cohort ID Period were excluded. Outcomes included SCE and event-related medical costs. SCE risk was compared using Cox proportional hazards models, while costs were compared via generalized linear models. Multivariate analyses controlled for age, gender, health coverage, geography, co-morbidities, concomitant medications, baseline lipids, and severity of initial ACE. **RESULTS:** A total of 1998 patients added NER (n = 145) or maintained SM (n = 1,853) and met all study criteria. NER patients were younger (57 ± 8 vs. 61 ± 11, P < 0.0001), less likely female (8% vs. 33%, P = 0.002), and had lower baseline LDL-C (81 ± 32 vs. 99 ± 41; P < 0.0001), HDL-C (34 ± 7 vs. 40 ± 9; P < 0.0001), and triglycerides (185 ± 118 vs. 208 ± 131; P = 0.0290). Compared to SM, NER patients had a 43% lower SCE risk (hazard ratio: 0.57, 95%CI: 0.35–0.94; P = 0.0274). Clinical findings corresponded with 56% reduction in adjusted annual event-related costs compared to SM (0.44; 95% CI: 0.25–0.80 p = 0.0068). **CONCLUSIONS:** Among patients requiring comprehensive lipid management, NER demonstrated lower SCE risk compared to SM, consequently reducing annual event-related medical costs following an ACE.

PCV9

RATE OF SUBSEQUENT CORONARY EVENTS AND DIRECT ECONOMIC OUTCOMES FOLLOWING AN ACUTE CORONARY EVENT BETWEEN PATIENTS AUGMENTING STATIN TO FURTHER REDUCE LDL-C VS. IMPROVING A COMPREHENSIVE LIPID PROFILE

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OBJECTIVES: Compare the annual subsequent coronary event rate (ASCER) and associated costs between patients initiating adjunct therapy with either niacin extended-release (NER) for comprehensive lipid panel management or ezetimibe (EZE) for continued LDL-C reduction after an acute coronary event (ACE). **METHODS:** Patients with an ACE between January 1, 2004 and May 31, 2009 were identified